UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,395	03/26/2004	Masaya Yamanouchi	0020-4935PUS2	8550

2292 7590 10/26/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,395	YAMANOUCHI ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/26/04, Figure 1* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/979,765.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/26/04, 11/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 are pending. Claims 1-4 are considered on the merits. Claim 5 is withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Applicant's election of Group I without traverse in Paper No. 9/13/06 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: The priority information in the first paragraph needs to be updated. Parent application 09/979765 has matured into US 6,794,154. Appropriate correction is required.

Claim Rejections - 35 USC § 112

SCOPE

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating focal glomerulosclerosis or glomerulonephritis by administering MCC-555, does not reasonably provide enablement for the treatment or prophylaxis of any renal disease by administering any PPAR agonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The nature of the invention is a treatment for renal disease not caused as a complication of diabetes comprising administering a PPAR agonist.

The claims are broadly drafted to include administration of all PPAR agonists as a therapeutic or prophylactic method for all renal diseases except as a result of complications of diabetes.

There are many peroxisome proliferator-activated receptors, some of which are designated alpha, beta, gamma, delta. These receptors have

different functions. For example PPAR alpha is involved in the regulation of lipid metabolism and inflammation, PPAAR beta is involved in embryonic development, implantation and bone formation. PPAR gamma is involved in adipogenesis, insulin sensitivity, cell cycle regulation and differentiation (Guan *et al.* [U]).

Applicants have demonstrated the use of one compound which is a known PPAR gamma agonist, MCC-555 in a mouse model of focal glomerulosclerosis. The claims, however, are broader than the administration of PPAR gamma agonists and claim the administration of any PPAR agonist to treat a renal disease, see Kazutaka *et al.* [V], where administration of a PPAR alpha agonist has no effect on glomerulonephritis. Thus, given the teachings of the art, it is unlikely that an agonist of PPAR alpha, for example, which is expressed in medullary collecting ducts, would have an effect of the glomerular mesangial cells which are involved in glomerulonephritis or glomerulosclerosis which is the type of renal disorder of the exemplified mouse model. Mesangial cells which are involved in albumin removal express PPAR gamma and are known to respond to at least some of the drugs classified as PPAR gamma agonists, specifically the antidiabetic drugs of the thiazolinediones (TZD) of which MCC-555 is one (Guan *et al.* [W]).

In fact, as late as 2006, it was discovered that in proximal renal tubular cells the TZDs exert an effect on protein handling which is independent of their PPAR gamma activity (Raviner *et al.* [X]). Also, a PPARgamma agonist 15d-PGJ2 had no effect in a model of experimental glomerulonephritis while the TZDs tested were effective (Panzer *et al.* [U2]). Thus, the claim broadly drafted to the use of all PPAR agonists or even of all PPAR gamma agonists to treat a protein handling type of renal dysfunction such as a glomerulonephritis or glomerulosclerosis is not fully supported by the disclose in view of the state of the art at time of filing and even to the present. Thus, the use of MCC-555 to treat focal glomerulosclerosis which is the type of adriamycin induced injury and glomerulonephritis, both of which are protein handling problems is considered to be enabled by the specification.

Regarding the claim to a prophylactic treatment, not even a diabetic nephropathy, which is the best studied renal disease can be prevented by the administration of PPAR gamma agonists (Simona *et al.* [V2]).

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in In re Fisher, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. Ex parte Humphreys, 24 USPQ2d, 1260.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,353,009 [IDS].

The claims are directed to the administration of PPAR agonist to treat renal disease not caused by diabetes.

US 6,353,009 discloses the administration of MCC 555 (col. 45, (6)) to treat renal disease associated with elevated uric acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0115699 [A] in light of Mukherjee *et al.* [W2].

The claims are directed to treatment or prevention of a renal disease not caused by diabetes comprising administering a PPAR agonist.

US 2002/0115699 discloses administering thiazolidinedione compounds which include isaglitazone [0002,0004,0009] to treat and prevent renal diseases including those not associated with diabetes [0005]. Although the reference is silent with regard to the PPAR agonist activity of the thiazolidinediones used to treat renal disease, this activity is inherent in this class of compounds. Thus, administering a thiazolidinedione which has known antidiabetic and renal treatment treating activity, necessarily incorporates administering PPARgamma agonist activity since these same compounds have multiple effects. This is an inherency rejection.

Mukherjee *et al.* disclose that thiazolidinediones in addition to their antidiabetic activity have PPARgamma agonist activity (abstract).

" To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See In re King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same

reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the administration of a PPAR agonist flows from the administration of thiazolidinedione class of compounds, which are known to have such activity.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone

number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
October 18, 2006